REMARKS

Status of the Claims

Claims 1-8, 17, and 31-33 are under examination.

Claims 3-8, 17, and 32-33 are amended herein. Support for the Claims is found in the specification as originally filed. More specifically, support for the recitation source in Claims 5 & 32 is found at least at page 4, paragraph [0048] of the published Application.

Claims 35-39 are newly added. Support for Claims 35-39 is found in the specification as originally filed. More specifically, support for Claim 35 is found at least at page 9-10, Examples 4 & 5 of the published Application; support for Claim 36 is found at least at page 6, paragraph [0062] of the published Application; support for Claims 37 & 38 is found at least at page 6, paragraph [0064] of the published Application; and support for Claim 39 is found at least at page 1, paragraph [0012] of the published Application.

Claims 1-2 are cancelled herein without prejudice. Claims 9-16, 18-30 and 34 are also cancelled herein as being drawn to non-elected subject matter. Applicants reserve the right to reintroduce cancelled subject matter, for example, in later-filed continuing application(s).

No new matter is introduced by the present amendment.

Office Comments Relating to Restriction Requirement

The Office Action stated,

> [t]he traversal is on the ground(s) that it would not place a serious burden on the Examiner to examine the subject matter of Group I, nucleic acid, and the subject matter of Group II, amino acids, together. This is not found persuasive because under PCT Rule 13.2, the inventions lack the same or corresponding special technical features for the following reasons: the Invention of Group I is not novel. WO 01/29233 A, WO 02/04018, and WO 01/68865 A all teach an isolated nucleic acid sequence encoding an Arthrobacter hsp70 protein.

Office Action at page 2, lines 3-10. Emphasis added.

For the record, Applicants' respectfully point out that WO 01/29233, WO 02/04018, and WO 01/68865 do not teach an isolated nucleic acid sequence encoding an *Arthrobacter* hsp70

protein. The disclosure of the above referenced international applications appears to relate to *Mycobacterium tuberculosis*.

Rejections under 35 U.S.C. § 112-2nd are Rendered Moot

The Office rejected Claims 1-8, 17 and 31-33 as allegedly indefinite. Of these claims, only Claims 3-8, 17, and 31-33 remain pending. Based on the foregoing amendment and the following remarks, Applicants' respectfully traverse the rejection.

By the present amendment, Applicants have cancelled Claims 1 and 2, accordingly, any asserted basis for the rejection is now rendered moot.

Regarding claim 3, the Office stated:

> Claim 3 is vague and indefinite due to the phrase 'a sequence having 85% homology thereto, or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO: 1'. .... The claim is also vague and indefinite because it is unclear what is encompassed by the phrase 'stringent [hybridization] conditions'.
>
> * * *
>
> Claim 3 is also vague and indefinite due the the phrase 'or a fragment thereof which encodes amino acid 162 to 365 of Hsp70" because it is vague and confusing

Office Action at pages 4-5.

Claim 3 is amended herein to enhance clarity. Moreover, as suggested by the Examiner, Applicants have amended claim 3 to expressly recite stringent hybridization conditions. Accordingly, any asserted basis for the rejection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.

Regarding claim 6, according to the Office, "Claim 6 is vague and indefinite due to the phrase 'wherein said antigen is IPNV VP2 or VP3'

As suggested by the Examiner, Claim 6 is amended herein to recite Infectious Pancreatic Necrosis Virus protein 2 or 3. Accordingly, any asserted basis for the rejection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.

In view of the amendments and arguments presented herein, Applicants respectfully request reconsideration and withdrawal of the rejection based upon §112, second paragraph.

Claim Objection

The Office objected to Claim 17, as depending from non-elected claim 11.

Claim 17 is amended to recite an open reading frame of SEQ ID NO:2, or its fully complementary sequence thereof. Moreover, as amended, Claim 17 is now an independent claim. Accordingly, any asserted basis for the objection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 112-1st are Rendered Moot

Asserted Lack of Enablement

The Office rejected Claim 2 as allegedly failing to comply with the enablement requirement. Based on the foregoing amendment and the following remarks, Applicants' respectfully traverse the rejection.

By the present amendment, Applicants have cancelled Claim 2, accordingly, any asserted basis for the rejection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.

The Office also rejected Claims 1-8, 17 and 31-33 as allegedly lacking enablement. Of these claims, only Claims 3-8, 17, and 31-33 remain pending. Based on the foregoing amendment and the following remarks, Applicants' respectfully traverse the rejection.

More specifically, the Office states that the specification is

> enabling for "an isolated polynucleotide comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365…

The Office further states that the specification "does not reasonably provide enablement for 'an isolated nucleic acid sequence encoding [any] Arthrobacter hsp70 protein', 'an isolated nucleic acid sequence which is 85% homologous to SEQ ID NO:1 or any isolated nucleic acid sequence which hybridizes under [any] stringent conditions to SEQ ID NO:1', nor is it

enabled for isolated nucleic acid sequences which encode sequences with at least 85% homology to SEQ ID NO:2 or amino acids 162-365 of SEQ ID NO:2."

Although Applicants disagree with the Office assertion regarding lack of enablement, in order to advance prosecution, Applicants have cancelled Claims 1-2 and amended Claim 3 to recite an isolated nucleic acid sequence comprising:

(a) the nucleic acid sequence of SEQ ID NO:1, or a fully complementary sequence thereof;

(b) nucleotide sequence which encodes amino acid residues162 to 365 of SEQ ID NO:2, or a fully complementary sequence thereof;

(c) nucleotides 291-2956 of SEQ ID NO:1, or a fully complementary sequence thereof;

(d) a nucleotide sequence encoding a polypeptide having at least 95% amino acid sequence identity to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is an *Arthrobacter* hsp70 protein, or the fully complementary sequence thereof; or

(e) a nucleotide sequence, or a fully complementary sequence thereof, which under stringent conditions hybridizes with the sequence of SEQ ID NO:1 or its complement, wherein the stringent condition comprises washing for 1 hour at 55° C with 1 X SSC and 0.1% SDS.

Accordingly, the asserted basis for the rejection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.

Although Applicants disagree with the Office assertion regarding lack of enablement with respect to the term "stringent conditions", in order to advance prosecution, Applicants have amended Claim 3 to at least set forth the reaction conditions encompassed by the stringent hybridization, *i.e.*, <u>washing for 1 hour at 55° C with 1 X SSC and 0.1% SDS</u>. However, Applicants draw the Examiner's attention to the specification at page 5, second paragraph, wherein Applicants have defined "stringent."

Further, although Applicants disagree with the Office assertion regarding lack of enablement with respect to "at least 85% homology to SEQ ID NO:2 or amino acids 162-365 of SEQ ID NO:2", in order to advance prosecution, Applicants have amended Claim 3 to at least recite <u>(d) a nucleotide sequence encoding a polypeptide having at least 95% amino acid sequence identity to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is an *Arthrobacter* hsp70 protein, or the fully complementary sequence thereof</u>. Enablement "is not precluded even

if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 947 (1987). Based upon the teachings contained within Applicants specification, and the advanced level of ordinary skill in the art, undue experimentation would not be required to obtain nucleic acids comprising a nucleotide sequence encoding a polypeptide having at least 95% amino acid sequence identity to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is an *Arthrobacter* hsp70 protein, or the fully complementary sequence thereof.

Further, the pending claims are enabled according to the *Wands* factors *(In re Wands* (8 USPQ2d 1400 (CAFC 1988)). The nature of the invention is nucleic acids encoding polypeptides having a determinable function (*i.e.,* heat shock protein), for which the state of the art and the relative level of skill in the art is advanced, and the predictability is such that one of skill could generate the claimed nucleic acids without undue experimentation. Taking these factors into consideration, the breadth of the pending claims is not undue. Applicants submit that the pending claims are enabled, and respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Regarding the rejection under 35 U.S.C. §112 as it relates to the claims directed to vaccine compositions, "[a] single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled." MPEP §2164.02. 'An example may be "working" or "prophetic."' MPEP §2164.02. "The results of the tests and examples should not normally be questioned by the examiner unless there is reasonable basis for questioning the results." MPEP §707.07(l).

First, Applicants point out that the nature of the invention as claimed in Claims 31 and 32 is vaccine compositions comprising a DNA expression vector comprising the isolated nucleic acid sequence of Claim 3, wherein said isolated nucleic acid sequence is operably linked to a transcriptional regulatory sequence. The state of the art and the relative level of skill in the art is advanced, and one of skill could generate such a vaccine composition without undue experimentation, based on the teachings of Applicants' specification.

Second, Applicants disagree with the Office contentions including the assertion that: "The results indicate that the VP2 sequence is necessary to achieve protection against virulent IPNV. Accordingly, only vaccines comprising pUKrsxHSP70- ipnVP2 and methods of protecting against disease caused by infection with IPNV (infectious pancreatic necrosis virus) are enabled."

In the Specification in Example 4 at page 25, lines 16-17, Applicants disclose that "the results indicate that all of the nucleic acid vaccines based on the VP2 sequence of IPNV are protective against challenge by the virus, including the hsp70-VP2 fusion." However, it does not follow that such a statement indicates that the VP2 sequence is necessary as incorrectly asserted by the Office.

Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *Ilybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 947 (1987). Generating fusion constructs encoding a *Arthrobacter* hsp70 polypeptide fused in-frame to a heterologous coding sequence (*e.g.,* VP2 or VP3), and evaluating the polypeptides produced by such constructs to prepare vaccine compositions as taught by Applicants' specification, would not require undue experimentation.

Taking these factors into consideration, the breadth of the pending claims is not undue. Applicants submit that the pending claims are enabled, and respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Regarding the rejection under 35 U.S.C. §112 as it relates to the claims directed to methods for preventing a disease in fish with the claimed vaccine compositions, Applicants respectfully disagree with the Office assertion that "[t]he results indicate that the VP2 sequence is necessary to achieve protection against virulent IPNV." In the Specification, Example 4 at page 25, lines 16-17, Applicants disclose that "the results indicate that all of the nucleic acid vaccines based on the VP2 sequence of IPNV are protective against challenge by the virus, including the hsp70-VP2 fusion." However, it does not follow that such a statement indicates that the VP2 sequence is necessary as incorrectly asserted by the Office.

Further, the pending claims are enabled according to the *Wands* factors *(In re Wands* (8 USPQ2d 1400 (CAFC 1988)). The nature of the invention as claimed in Claim 33 is a

method of preventing disease in a fish, the method comprising administering to said fish the vaccine composition of Claim 32. The specification gives several examples of disease, and these are further provided in dependent claims. The level of skill in the art is advanced, and such a person could take the vaccine described herein and evaluate any number of diseases effecting fish without undue experimentation. Taking these factors into consideration, the breadth of the pending claims is not undue. Applicants submit that the pending claims are enabled, and respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Asserted Lack of Written Description

The Office rejected Claims 1-8, 17, and 31-33 as allegedly failing to comply with the written description requirement. Of these claims, only Claims 3-8, 17, and 31-33 remain pending. Based on the foregoing amendment and the following remarks, Applicants' respectfully traverse the rejection.

According to the Examiner, "only 'an isolated polynucleotide comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which encodes the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365', but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph."

Although Applicants disagree with the Office assertion regarding failure to comply with the written description requirement, in order to advance prosecution, Applicants have cancelled Claims 1-2 and amended Claim 3 to recite an isolated nucleic acid sequence comprising:

(a) the nucleic acid sequence of SEQ ID NO:1, or a fully complementary sequence thereof;

(b) nucleotide sequence which encodes amino acid residues162 to 365 of SEQ ID NO:2, or a fully complementary sequence thereof;

(c) nucleotides 291-2956 of SEQ ID NO:1, or a fully complementary sequence thereof;

(d) a nucleotide sequence encoding a polypeptide having at least 95% amino acid sequence identity to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is an *Arthrobacter* hsp70 protein, or the fully complementary sequence thereof; or

(e) a nucleotide sequence, or a fully complementary sequence thereof, which under stringent conditions hybridizes with the sequence of SEQ ID NO:1 or its complement, wherein the stringent condition comprises washing for 1 hour at 55° C with 1 X SSC and 0.1% SDS.

Accordingly, the asserted basis for the rejection is now rendered moot, and Applicants respectfully request that the rejection be withdrawn.